DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 14, 2014

Siemens Medical Solutions, USA, Inc.
% Ms. Eve Davis
Regulatory Affairs Specialist
51 Valley Stream Parkway D02
MALVERN PA 19355

Re: K140232
Trade/Device Name: syngo® CT 2014A (SOMARIS/5 VB42) for SOMATOM Emotion & SOMATOM Sensation family CT systems
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: August 15, 2014
Received: July 6, 2014

Dear Ms. Davis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K140232

Device Name
syngo® CT 2014A (SOMARIS/5 VB42) for SOMATOM Emotion & SOMATOM Sensation family CT systems

Indications for Use *(Describe)*
The SOMATOM Emotion and SOMATOM Sensation family CT systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes" taken at different angles.

(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

Submitted by:
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: July 15, 2014

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

**1. General Information**

**Importer/Distributor:**
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

**Establishment Registration Number:**
2240869

**Manufacturing Site:**
SIEMENS SHANGHAI, MEDICAL EQUIPMENT LTD.
278 Zhou Zhu Rd
Shanghai, CHINA 201318

**Establishment Registration Number:**
3003202425

**2. Contact Person:**

Eve Davis
Regulatory Affairs Specialist, Regulatory Affairs Submissions
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway D02
Malvern, PA 19355-1406
Phone: (610) 219-7133 Fax: (610) 448-1778
Email: eve.davis@siemens.com

**3. Device Name and Classification**

| | |
|---|---|
| **Product Name:** | *syngo*® CT 2014A (SOMARIS/5 VB42) for SOMATOM Emotion & SOMATOM Sensation family CT systems |
| **Propriety Trade Name:** | *syngo*® CT 2014A (SOMARIS/5 VB42) for SOMATOM Emotion & SOMATOM Sensation family CT systems |
| **Classification Name:** | Computed Tomography X-ray System |
| **Classification Panel:** | Radiology |
| **CFR Section:** | 21 CFR §892.1750 |
| **Device Class:** | Class II |
| **Product Code:** | JAK |

**4. Substantial Equivalence:**

Siemens *syngo*® CT 2014A (SOMARIS/5 VB42) for SOMATOM Emotion & SOMATOM Sensation family CT systems is substantially equivalent to the following medical devices in commercial distribution:

| Predicate Devices | FDA Clearance Number | FDA Clearance Date |
|---|---|---|
| *syngo*® CT 2013A (SOMARIS/5 VC20B) | K133424 | January 17, 2014 |
| SOMATOM Project P30F/ Sensation 64 | K040655 | April 2, 2004 |
| SOMATOM Project P30L/ Sensation Open | K040577 | March 22, 2004 |
| SOMATOM P30 CT Systems/ Sensation | K013522 | November 07, 2001 |

**5. Device Description:**

*syngo*® CT 2014A (SOMARIS/5 VB42) is a new scanning software version for the following, already commercially available, systems:

- SOMATOM Emotion 6 CT System
- SOMATOM Emotion 16
- SOMATOM Project P30F/Sensation 64
- SOMATOM Project P30L/Sensation Open
- SOMATOM P30 CT/Sensation

The system software is a command-based program used for patient management, data management, X-ray scan control, image reconstruction, and image archive/evaluation. This new software version, *syngo*® CT 2014A (SOMATOM Emotion & SOMARIS/5 VB42), supports bug fixing and an upgrade for the existing commercially available SOMATOM Sensation family CT systems for better maintenance.

The SOMATOM Emotion and SOMATOM Sensation family CT systems are whole body X-ray Computed Tomography Systems. They produce CT images in DICOM format, which can be used by post-processing applications commercially distributed by Siemens and other vendors.

**6. Summary of Technical Characteristics of the Subject Device as Compared with the Predicate Device:**

There are no significant changes in the materials, energy source, or technological characteristics when compared to the predicate devices for *syngo*® CT 2014A (SOMARIS/5 VB42) for SOMATOM Emotion & SOMATOM Sensation family CT systems. The imaging components (tube, collimator, detector, and DAS) are the same as the predicate devices.

In addition to the bug fixing and upgrade, the new software version *syngo*® CT 2014A (SOMARIS/5 VB42) supports features which already exist on other commercially available SOMATOM Emotion and SOMATOM Sensation Family CT

Systems. These features are now also provided to the above mentioned systems, which have been installed or were in use prior to their introduction. These features are:

- Dose MAP
- e-Start Functionality
- IRIS

## 7. Nonclinical Testing:

The SOMATOM Emotion and SOMATOM Sensation family CT systems configured with software version *syngo*® CT 2014A (SOMARIS/5 VB42) are designed to fulfill the requirements of the following standards:

| Recognition Number | Product Area | Title of Standard | Reference Number & Date | Publication Date | Standards Development Organization |
|---|---|---|---|---|---|
| 5-40 | General | Medical devices – Application of risk management to medical devices | 14971 Second Edition 2007-03-01 | 08/20/2012 | ISO |
| 13-8 | Software | Medical device software – Software life cycle processes | 62304 First edition 2006-05 | 08/20/2012 | IEC |
| 5-41 | General | Medical electrical equipment – Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems, edition 1.1 | 60601-1-4: 2000 Consol.Ed 1.1 | 09/08/2009 | IEC |
| 12-218 | Radiology | Digital Imaging and Communications in Medicine (DICOM) Set | PS 3.1-3.15, 2001 | 3/18/2011 | NEMA |
| 12-222 | Radiology | Evaluation and routine testing in medical imaging departments - Part 3-5: Acceptance tests - Imaging performance of computed tomography X-ray equipment | 61223-3-5 First edition 2004-08 | 03/18/2011 | IEC |
| 12-226 | Radiology | Evaluation and routine testing in medical imaging departments - Part 2-6: Constancy tests - Imaging performance of computed | 61223-2-6 Second Edition 2006-11 | 02/28/2011 | IEC |

| | | | | | |
|---|---|---|---|---|---|
| | | tomography X-ray equipment | | | |
| 12-225 | Radiology | Computed Tomography Dose Check | XR-25 | 03/18/2011 | NEMA |
| 5-78 | General | A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment—Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) | ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and a2:2010/(R)2012 | 01/14/2014 | AAMI ANSI |
| 5-53 | General | Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests | 60601-1-2 Edition 3:2007-03 | 01/30/2014 | IEC |
| 5-54 | General | Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests (Edition 3) | 60601-1-2:2007/(R)2012 | 01/30/2014 | AAMI ANSI IEC |
| 12-257 | Radiology | Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for X-ray equipment for computed tomography | 60601-2-44 Edition 3.0 2009-02 | 01/14/2014 | IEC |

Non-clinical tests were conducted for the SOMATOM Emotion & SOMATOM Sensation family CT systems configured with software version *syngo*® CT 2014A (SOMARIS/5 VB42) during product development. The modifications described in this Premarket Notification were supported with verification/validation as well as phantom testing.

The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results support the conclusion that all of the software specifications have met the acceptance criteria. Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence.

FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005, was adhered to.

**8. Indications for Use:**

The SOMATOM Emotion and SOMATOM Sensation family CT systems are intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes* taken at different angles.

(*spiral planes: the axial planes resulted from the continuous rotation of detectors and x-ray tube, and the simultaneous translation of the patient.)

**9. General Safety and Effectiveness Concerns:**

The device labeling contains instructions for use as well as necessary cautions and warnings to provide for safe and effective use of the device.

Risk management is ensured via a hazard analysis. Potential hazards are controlled during development, verification and validation testing. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and standards.

**10. Conclusion as to Substantial Equivalence**

In summary, Siemens is of the opinion that *syngo*® CT 2014A (SOMARIS/5 VB42) for SOMATOM Emotion & SOMATOM Sensation family CT systems does not introduce any new potential safety risk, and is substantially equivalent to and performs as well as the predicate devices.